86-842

Supreme Court, U.S.
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No. .....

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1986

SHILEY INCORPORATED,
Appellant,

VS.

JAMES FOGARTY CORRIGAN, BRETT JAMES CORRIGAN,
and SCOTT GRANT CORRIGAN,
Appellees.

On Appeal from the California Court of Appeal

JURISDICTIONAL STATEMENT

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QUESTIONS PRESENTED

1. Whether a state appellate court may apply a standard patently inconsistent with this Court's decision in *Piper Aircraft Co. v. Reyno,* 454 U.S. 235 (1981), so as to reverse a lower court's exercise of discretion to stay proceedings on forum non conveniens grounds in a wrongful death/products liability action brought by foreign plaintiffs with regard to a product only exported in foreign commerce.

2. Whether a state appellate court may apply a rule which is hostile to federally-established principles of international comity so as to reverse a lower court's exercise of discretion to stay proceedings on forum non conveniens grounds in a wrongful death/products liability action brought by foreign plaintiffs with regard to a product only exported in foreign commerce.

STATEMENT UNDER RULE 15.1(b)

Appellees Corrigan brought this action in California Superior Court erroneously suing Appellant Shiley Incorporated ("Shiley") as "Bjork Shiley Corporation, Shiley Corporation" and also suing Does 1 through 40, inclusive. As appellants in the California Court of Appeal, the Corrigans named as respondents all defendants as originally sued. However, the Corrigans and Shiley are the only parties ever to have appeared in this action.

STATEMENT UNDER RULE 28.1

Shiley is a wholly-owned, first tier subsidiary of Pfizer Inc. ("Pfizer"), a publicly-held corporation.[1]

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[1]The following are the subsidiaries and affiliates of Shiley and Pfizer not wholly-owned, directly or indirectly, by either Shiley or Pfizer: Pfizer Laboratories (Bangladesh) Ltd.; Pfizer Egypt S.A.A.; PT Pfizer Indonesia; Pfizer Laboratories Ltd. [Pakistan]; Pfizer Ltd. [Sri Lanka]; Pfizer Bioquimicos S.A. [Venezuela]; Foster & Hug K.G. [Germany]; Heinrich Mack Nachf [Germany]; Pfizer Quigley Korea Ltd.; Laboratoires Pfizer S.A. [Morocco]; Jacquet Orthopedie S.A. [Switzerland]; Pfizer Hospital Products Group Ltd. [United Kingdom]; Pfizer Ltd. [India]; Pfizer Korea Ltd.; Agricare Ltd. [Ghana]; Pfizer Ltd. [Ghana]; Kronans Droghandel Aktiebolag [Sweden]; Livestock Feeds Ltd. [Nigeria]; Mezquital HyN S.A. de R.L. [Mexico]; Orotal S. d R.L. de C.V. [Mexico]; Directed Energy Inc.; Vanart Metropolitana S.A. de C.V. [Mexico]; Oncogene Sciences Inc.; Meditron Inc.; Angiomedics Inc.; Camino Laboratories Inc.; Cardiovascular Devices Inc. In addition, Pfizer has a minority partnership interest in Dekalb Pfizer Genetics (subsidiaries are: Dekalb Argentina S.A.; Dekalb Italiana S.p.A.; Sementes Selecionadas AD Ltda.; Dekalb Canada Ltd.; Sockalb S.A. [France]; Marchetto & Co. S.p.A. [Italy]; Semillas Hibridas de Mexico, S. de R.L.; Semillas Agricolas S.A. [Spain]; Charoen Seeds Co. Ltd. [Thailand]; Deras Italy).

STATEMENT UNDER RULE 28.4

This appeal raises the question of the validity of a California statute as applied. Accordingly, 28 U.S.C. § 2403(b) may be applicable to this proceeding. A copy of this Jurisdictional Statement is being served upon the Attorney General of California.

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JURISDICTIONAL STATEMENT

DECISIONS BELOW

The opinion of the California Court of Appeal (Appendix A *infra*) is reported at 182 Cal. App. 3d 166, 227 Cal. Rptr. 247. The order of the Supreme Court of California denying a petition for discretionary review (Appendix B *infra*) is without opinion but is recorded in 24 Cal. Official Reports (Official Advance Sheets), "Cumulative Subsequent History" at 90 (1986). The order of the California Court of Appeal denying a petition for rehearing (Appendix E *infra*) is without opinion and is as yet unreported. The order of the California Superior Court (Appendix D *infra*) is unreported.

JURISDICTION

The final judgment of the California Court of Appeal from which appeal is taken was entered on June 9, 1986, and modified on June 19, 1986 (p. A-1 *infra*). The order of the Supreme Court of California denying a timely petition for discretionary review was entered on August 20, 1986 (p. B-1 *infra*). The notice of appeal to this Court from the judgment of the California Court of Appeal (Appendix F *infra*) was filed on November 12, 1986, with a copy filed the same day in the California Superior Court, the court possessed of the record.[2]

Jurisdiction of this appeal is conferred upon this Court by 28 U.S.C. § 1257(2). This appeal concerns California's statutory provision with respect to forum non conveniens, California Code of Civil Procedure § 410.30(a). As construed and applied by the California Court of Appeal, the highest court below in which a decision could be had, this statute is repugnant to the Constitution and laws of the United States. This construction and application was so challenged and drawn into question below.[3]

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[2]The remittitur notice is set forth in Appendix C *infra*.

[3]In construing and applying § 410.30(a) to reverse the trial court's forum non conveniens order, the California Court of Appeal relied on the official comment to the statute (Cal. Civ. Proc. Code § 410.30, Judicial Council comment (West 1973)) and the interpretation of the comment by *Holmes v. Syntex Laboratories, Inc.*, 156 Cal. App. 3d 372, 202 Cal. Rptr. 773 (1984). Although the court below did not expressly come to grips with the merits of Shiley's federal question challenge to application of the statute to reverse the trial court order, this sub silentio rejection of the challenge is a decision in favor of the statute's validity. *See Lawrence v. State Tax Commission*, 286 U.S. 276, 282-283 (1932).

CONSTITUTIONAL PROVISIONS INVOLVED

United States Constitution, Article I, Section 8, Clause 3

[The Congress shall have the Power] To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes; . . .

United States Constitution, Article VI, Clause 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

United States Constitution, Article I, Section 10

(This provision is set forth in Appendix G *infra*.)

STATUTES INVOLVED

California Code of Civil Procedure Section 410.30(a)

When a court upon motion of a party or its own motion finds that in the interest of substantial justice an action should be heard in a forum outside this state, the court shall stay or dismiss the action in whole or in part on any conditions that may be just.

United States Code, Title 21, Sections 360e, 360k, 381(d)

(These statutes are set forth in Appendix H *infra*.)

STATEMENT OF THE CASE

By this appeal, Shiley challenges the constitutionality of California's forum non conveniens statute as applied.

The plaintiffs are Australians who brought this wrongful death action in California state court against Shiley, a California manufacturer of high-technology medical devices including various models of the Bjork-Shiley artificial heart valve, which are widely implanted throughout the world. The plaintiffs' decedent, also an Australian, died in Australia allegedly as a result of the malfunction of a Bjork-Shiley valve which was implanted during surgery in Australia by an Australian surgeon. The particular valve model in question was specifically approved by the United States Food and Drug Administration for export to Australia but was never sold or distributed in the United States.[4]

Relying on the doctrine of forum non conveniens, Shiley moved for the dismissal of this action on the ground that it should be brought in Australia. In connection with its motion, Shiley stipulated to (1) submit to the jurisdiction of the appropriate Australian court, (2) comply with all discovery orders of the Australian court, (3) exercise its best efforts, enforceable according to the discretion of the Australian court, to make any ten past and present Shiley employees designated by plaintiffs available to testify at trial in Australia, and (4) pay any judgment rendered in the Australian action.

Shiley contended that Australian trial is essential to the availability of testimony from key nonparty Austra-

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[4]The valve model in question is the Bjork-Shiley cardiac valve prosthesis with convexo-concave disc opening to a 70-degree angle ("70-degree valve"). The valve consists of a pyrolytic carbon disc which tilts freely inside a ring with retaining struts made of cobalt-based alloy. The convexo-concave disc was first introduced for its improved blood flow characteristics and consequent reduction in clotting complications. During the year following the incident in this case, the FDA withdrew export approval for the 70-degree valve.

lian witnesses and to Shiley's ability to implead as cross-defendants Australian medical personnel who are likely responsible for the malfunction of the valve.[5] Shiley further based its motion on Australia's substantially greater public interest in this case, making appropriate Australian [illegible] and — under California's "governmental interest" [illegible]ce of law rule — the application of Australian law.

Declarations of Australian lawyers submitted by the parties established that the plaintiffs may bring a wrongful death action against Shiley in the Supreme Court of New South Wales, Australia, proceeding under a negligence cause of action.[6] However, strict products liability

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[5]Although other 70-degree valves have fractured from metal fatigue, Shiley presented evidence that mishandling of the valve by the Australian medical personnel may have led to the fracture in this case. Apparently, the hospital followed a practice of removing 70-degree valves from the rigid containers in which they were shipped from Shiley, which were specially designed to protect the valves from damage. The hospital then wrapped 70-degree valves in paper table napkins and paper bags and apparently sterilized them in this condition. This procedure was contrary to Shiley's written instructions, which accompanied each 70-degree valve, stating the valve should be sterilized in its protective container. The crude paper wrapping used by the hospital did not protect the structural integrity of the valve, but subjected it to external pressures which may have damaged the sensitive positioning of the outflow strut and led to the fracture in this case.

Trial in Australia would enable Shiley to subpoena the nonparty witnesses to present its defense and implead the potentially culpable third parties for contribution and indemnity. If trial is held in California, any subsequent contribution and indemnity action which Shiley might bring in Australia would be limited to damages available under Australian law.

[6]New South Wales' applicable statute of limitations period is six years and does not expire until September, 1988.

is unavailable as a theory of recovery, and the elements of damages available for wrongful death under Australian law are more restricted than those available under California law.

Shiley further argued in both its moving and reply memoranda of points and authorities submitted to the trial court that because of the foreign relations and foreign commerce concerns raised by this litigation, its motion should be granted under international comity and forum non conveniens doctrines established by the federal courts. These papers were subsequently submitted to the California Court of Appeal under Cal. R. Ct. 5.1 and to the California Supreme Court under Cal. R. Ct. 28(b). The trial court ordered the action stayed on the ground of forum non conveniens pursuant to Cal. Civ. Proc. Code § 410.30(a).[7]

The plaintiffs appealed the decision of the trial court to the California Court of Appeal. They claimed that California products liability law would apply if the case were tried in California, that trial in Australia would disadvantage the plaintiffs in terms of applicable substantive law and that, therefore, the decision of the California Court of Appeal in *Holmes v. Syntex Laboratories, Inc.*, 156 Cal. App. 3d 372, 202 Cal. Rptr. 773 (1984), required reversal.[8] *Holmes* expressly refused to follow this Court's

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[7]Under § 410.30(a), a trial court may grant a forum non conveniens motion by either stay or dismissal. In this case, the trial court ordered a stay of proceedings on condition that plaintiffs could still bring their action in Australia (p. D-1 *infra*).

[8]*Holmes* reversed the forum non conveniens dismissals of products liability actions brought in California state court by British users of contraceptive drugs manufactured and distributed in Great Britain but allegedly developed in California. *Holmes* excoriated Great Britain for its negligence standard of products liability and held that

decision in *Piper Aircraft Co. v. Reyno*, 454 U.S. 235 (1981), *reh'g denied*, 455 U.S. 928 (1982). *Reyno* affirmed the forum non conveniens dismissals of products liability actions brought on behalf of foreign citizens where the remedy available in the foreign forum was less advantageous to the claimants.

Shiley criticized *Holmes* for — among other reasons — its violation of the rationale and holding of *Reyno*, urged affirmance under both California decisions and *Reyno* and asserted that controlling federal decisions concerning international comity direct that California defer to Australia for adjudication of this action.

The California Court of Appeal concluded that a trial court would apply California substantive law given Shiley's California residence and construed Cal. Civ. Proc. Code § 410.30(a) to require reversal of the stay order based upon its finding that the plaintiffs would be disadvantaged by having to try their case under Australian law. The court dismissed the federal questions sub silentio and simply observed that "respondents urge that *Holmes* is anomalous and other decisions, including those handed down in federal court, mandate that the stay

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under Cal. Civ. Proc. Code § 410.30(a) the absence of strict products liability in that country rendered it an unsuitable alternative forum and thereby required retention of the proceedings in California. 156 Cal. App. 3d at 379, 383-387. As with the present case, the Supreme Court of California refused to exercise its discretion to review. 156 Cal. App. 3d at 392. The only other reported California decision since *Holmes* to address the forum non conveniens doctrine in the international products liability context, *Rehm v. Aero Engines, Inc.*, (formerly 164 Cal. App. 3d 715), 210 Cal. Rptr. 594 (1985), affirmed dismissal. However, the Supreme Court of California ordered the opinion not published (164 Cal. App. 3d 736), thereby stripping the case of precedential authority pursuant to Cal. R. Ct. 976(c)(2), 977(a).

imposed by the trial court be upheld." California Court of Appeal opinion at p. A-9 *infra,* 182 Cal. App. 3d at 176, 227 Cal. Rptr. at 252.

Shiley petitioned the Supreme Court of California for review of the decision of the California Court of Appeal, citing state cases supporting reversal and *Reyno* and its progeny. Shiley again urged that California should defer to Australia to apply its law to this case in light of principles of international comity and the federal government's exclusive authority to regulate foreign relations and commerce. The Supreme Court of California denied the petition for discretionary review without opinion (p. B-1 *infra*).

GROUNDS FOR PLENARY CONSIDERATION

This case presents substantial questions concerning foreign commerce, foreign relations and separation of powers which should be promptly and definitively resolved by this Court. The judgment below is plainly at odds with the decision of this Court in *Piper Aircraft Co. v. Reyno*, 454 U.S. 235 (1981),[9] and with doctrine set

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[9]When considered with the opinion below, decisions in the courts of other states demonstrate conflict and confusion over whether *Reyno* is controlling in state courts. *See Couch v. Chevron International Oil Co.*, 672 S.W.2d 16, 18 (Tex. Ct. App. 1984) (federal forum non conveniens doctrine found controlling in dismissal of foreign-plaintiff wrongful death action sounding in admiralty), *reh'g denied on other grounds*, 682 S.W.2d 534 (Tex. 1984); *Alcantara v. Boeing Co.*, 41 Wash. App. 675, 705 P.2d 1222 (1985) (affirming dismissal of international products liability litigation; forum non conveniens law controlling in federal courts implicitly found to be the same in state court, but unclear whether source of law applied in state court is state or federal), *petition for review denied*, 104 Wash. 2d 1022 (1985); *Jones v. Searle Laboratories*, 93 Ill. 2d 366, 444 N.E.2d 157, 67 Ill. Dec. 118 (1982) (affirming dismissal of foreign-plaintiff products

forth by the United States Court of Appeals for the Ninth Circuit in *Timberlane Lumber Co. v. Bank of America, N.T. & S.A.*, 549 F.2d 597 (9th Cir. 1976).

Summary of Argument for Plenary Review

California has unilaterally imposed a significant burden on the foreign commerce of the United States. As interpreted and applied, the California statute at issue subjects high-technology exports to the terms and conditions of California's liberal products liability law and precludes the forum non conveniens dismissal of foreign-plaintiff actions where the alternative forum would apply a law less advantageous to the plaintiffs. The effects are that (1) American exporting firms are denied the ability to compete in overseas markets with foreign manufacturers on the same liability terms and (2) foreign governments are unable to pursue tort liability policies which encourage needed imports from leading U.S. producers of high-technology medical products.

These burdens on foreign commerce and foreign relations are not incidental and unintended consequences of California's adjudication of cases coming within its jurisdiction. *Cf. Edgar v. Mite Corp.*, 457 U.S. 624, 640 (1982) (only incidental regulation of interstate commerce by states is permissible; direct regulation prohibited).

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liability claims, citing state and federal cases; basis for holding unclear), *reh'g denied*, (1983); *Bergquist v. Medtronic, Inc.*, 379 N.W.2d 508 (Minn. 1986) (dismissing foreign-plaintiff action brought against Minnesota artificial heart valve manufacturer, following *Reyno*, though apparently as a matter of choice); *Armadora Naval Dominicana, S.A. v. Garcia*, 478 So. 2d 873 (Fla. Dist. Ct. App. 1985) (ordering forum non conveniens dismissal of foreign-plaintiff maritime injury claim; citing *Reyno*, several other federal cases and one state case; basis for holding unclear).

Rather, under the application of Cal. Civ. Proc. Code § 410.30(a) below, California has made a conscious determination to regulate the foreign marketing of exports and to deprive a foreign sovereign of the ability to adjudicate an action where California deems the applicable laws of the foreign government to be substantively inferior to its own.

This effort by California to expand the reach of its products liability policies is at odds with the decision of this Court in *Piper Aircraft Co. v. Reyno*, 454 U.S. 235 (1981). On very similar facts, this Court held in *Reyno* that the advantage of favorable American products liability laws does not automatically entitle foreign plaintiffs to bring actions in the United States against American manufacturers. 454 U.S. at 247.[10] In *Reyno*, this Court established a federal forum non conveniens doctrine which limits the aggressive reach of state products liability laws where foreign commerce exports are concerned. California's action in the court below is contrary to the holding of *Reyno* and, accordingly, is ultra vires. As articulated by this Court in *Japan Line, Ltd. v. County of Los Angeles*, 441 U.S. 434, 451 (1979), any state action which prevents the federal government from "speaking with one voice" when regulating foreign commerce is unconstitutional.

This Court determined in *Reyno*, 454 U.S. at 260, that the foreign jurisdiction has the predominant public interest in litigation where, as here, injury occurred abroad to foreign nationals and the only connection of the case with the United States is the American location of the defen-

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[10]Indeed, if the decision below is allowed to stand, dramatically different results in diversity cases will turn solely on whether an action is removed to federal court. *See infra* note 12 and discussion re *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), *infra* pp. 16-18.

dant manufacturer. The holding in *Reyno* gives credence to the decision of the Ninth Circuit Court of Appeals in *Timberlane Lumber Co. v. Bank of America, N.T. & S.A.*, 549 F.2d 597 (9th Cir. 1976). In analyzing the appropriate limits on the extraterritorial reach of the federal antitrust laws, the *Timberlane* court held that as a matter of international comity American courts should not exercise jurisdiction over litigation where the interests of the United States are not sufficiently strong vis-a-vis those of the other nation concerned. *Timberlane,* 549 F.2d at 613-615.

Nevertheless, even though the Constitution entrusts exclusive authority over foreign relations to the federal government, the court below saw fit to eschew federally-established principles of international comity in favor of vindicating what one California appellate court has described as the state's "interest in regulating the foreign marketing of defective products alleged to have been developed in California." *See Holmes v. Syntex Laboratories, Inc.,* 156 Cal. App. 3d 372, 389, 202 Cal. Rptr. 773, 784 (1984) (cited in Court of Appeal opinion at pp. A-9, A-15-16 *infra,* 182 Cal. App. 3d at 175, 180, 227 Cal. Rptr. at 252, 255). Thus, *Holmes* and the judgment below are in conflict with the Ninth Circuit and other Circuit Courts of Appeals which have followed the principles enunciated in *Timberlane.*[11]

The California Court of Appeal's insistence on retaining jurisdiction over litigation involving exported products, even where a trial court has determined that another forum is more appropriate, disrupts the ability of foreign

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[11] *See, e.g., Montreal Trading Ltd. v. Amax Inc.,* 661 F.2d 864, 869-870 (10th Cir. 1981), *cert. denied,* 455 U.S. 1001 (1982); *Mannington Mills, Inc. v. Congoleum Corp.,* 595 F.2d 1287, 1296-1297 (3d Cir. 1979).

governments to encourage American imports by limiting potential tort liability. Moreover, this interference with foreign commerce exports — if allowed to continue — will choke the competitiveness of American high-technology exports with foreign-made products in overseas markets.

I

CALIFORNIA'S OPPOSITION TO THE FEDERAL FORUM NON CONVENIENS DOCTRINE ESTABLISHED BY *PIPER AIRCRAFT CO. v. REYNO* UNCONSTITUTIONALLY USURPS FOREIGN COMMERCE POWER GRANTED EXCLUSIVELY TO THE FEDERAL GOVERNMENT AND THREATENS THE PRESSING NATIONAL INTEREST IN COMPETITIVE EXPORTS.

A. To Prevent a Mass Circumvention of Federally-Established Forum Non Conveniens Doctrine Set Forth by this Court in *Piper Aircraft Co. v. Reyno*, the Judgment Below Must Be Reversed.

The facts of *Reyno* are strikingly similar in pertinent respects to those of the present case. In *Reyno*, wrongful death actions were brought against the American manufacturers of an airplane and its component parts following the crash of the plane in Scotland. All of the decedents and their heirs were Scottish citizens and residents. The actions were commenced, as was the present case, in the California Superior Court for Los Angeles County. After removal for diversity of citizenship,[12] the actions were transferred to the United States District Court for the Middle District of Pennsylvania, the state

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[12]The instant action was not removable as Shiley is a California resident corporation. *See* 28 U.S.C. §§ 1332(c), 1441(b).

where defendant Piper Aircraft Co. manufactured the airplane.

The district court granted motions to dismiss on the ground of forum non conveniens in favor of an alternative forum in Scotland. The Third Circuit Court of Appeals reversed, relying on the fact that the substantive law in the Scottish forum would be less favorable to the claimants. Specifically, Scotland — like New South Wales, Australia — does not have strict products liability and allows only limited wrongful death damages.

This Court reversed, holding that the possibility of an unfavorable change in law does not, by itself, bar dismissal and that the district court had not abused its discretion in granting the forum non conveniens motions. 454 U.S. at 238-240.

Numerous cases have abided by *Reyno,* dismissing products liability and related tort litigation brought by foreign plaintiffs in the United States against American defendants in favor of trial of each case in the foreign country of the plaintiff's residence where the injury occurred and the cause of action arose. *See, e.g., In Re Union Carbide Corporation Gas Plant Disaster at Bhopal, India in December, 1984,* 634 F. Supp. 842 (S.D.N.Y. 1986); *Fraizer v. St. Jude Medical, Inc.,* 609 F. Supp. 1129 (D. Minn. 1985) (Denmark); *Abiaad v. General Motors Corp.,* 538 F. Supp. 537 (E.D. Pa. 1982), *aff'd mem.,* 696 F.2d 980 (3d Cir. 1982) (United Arab Emirates). *See also Harrison v. Wyeth Laboratories, etc.,* 510 F. Supp. 1 (E.D. Pa. 1980), *aff'd mem.,* 676 F.2d 685 (3d Cir. 1982) (Great Britain).

The judgment below, however, would circumvent the holding of *Reyno,* leading to a new wave of foreign-plaintiff litigation in state courts. Trial courts would be

powerless to conduct the case-by-case inquiry into fairness and public interests which *Reyno* mandated. 454 U.S. at 241 n.6, 255 (citing factors set forth in *Gulf Oil Corp. v. Gilbert,* 330 U.S. 501, 508-509 (1947)). As observed by this Court in *Reyno,* American courts are already extremely attractive to foreign plaintiffs; the assurance of obtaining the advantage of the strict products liability law of California or other states would further increase the flow of litigation into the United States. *See Reyno,* 454 U.S. at 252. Significantly, the present volume of American exports (*see infra* p. 19) portends an influx of foreign-plaintiff products liability litigation of massive proportions.

This case presents what is perhaps a *singular opportunity* for the Court to resolve this issue. A refusal by this Court to grant plenary review of the instant action, when considered with the published opinion of the California Court of Appeal below and the parallel California Court of Appeal decision in *Holmes,* would make extremely unlikely the prospect that any California trial court would ever again exercise its discretion to grant a forum non conveniens motion in an action brought by a foreign plaintiff. Moreover, this would gravely discourage defendants from even asserting the principles of *Reyno* in the courts of California or any other state which follows California authority.

As indicated at pp. 18-20 *infra,* the threat to the global competitiveness of American exports is acute. This case is the timely vehicle for vindicating the *Reyno* doctrine as a bar to the imposition of undue burdens on the foreign commerce of the United States by the several states.

B. Federally-Established Forum Non Conveniens Doctrine Is Binding on State Courts in Litigation Arising from Foreign Commerce Exports.

The constitutional authority to regulate commerce with foreign nations is entrusted exclusively to the federal government, and "may not be limited, qualified or impeded to any extent by state action." *University of Illinois v. United States,* 289 U.S. 48, 56-57 (1933). The Commerce Clause is a free trade charter which preempts state interference, even in the absence of an affirmative Congressional pronouncement.[13] *Japan Line,* 441 U.S. at 454; *Boston Stock Exchange v. State Tax Commission*, 429 U.S. 318, 328 (1977). Here, California would burden American export commerce by inviting foreign users of such products to take advantage of liberal American products liability laws by bringing lawsuits in state courts, and by prohibiting trial courts from employing the usual discretionary doctrine of forum non conveniens to combat the abuse of forum shopping.

This Court emphasized in *Japan Line* that preemption of state interference with and burdens on commerce is

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[13]This case may in fact involve more than dormant Foreign Commerce Clause preemption. The substantial differences between standards for FDA approval to market an artificial heart valve within the United States and the standards for federal export permission suggest an affirmative Congressional desire to promote the export of artificial heart valves and other Class III medical devices, subsequent withdrawal of FDA permission to export the 70-degree valve notwithstanding. *Cf.* 21 U.S.C. § 381(d) (controlling export of medical devices) with 21 U.S.C. § 360e (controlling premarket approval for domestic distribution of life-supporting (Class III) medical devices). 21 U.S.C. § 360k *expressly* preempts state and local regulation of medical devices subject to the Federal Food, Drug, and Cosmetic Act absent specific federal administrative approval. (§§ 360e, 360k, and 381(d) are set forth in Appendix H *infra.*)

applied much more vigorously in the international — as opposed to the interstate — context. 441 U.S. at 446-454. In *Japan Line*, a California ad valorem property tax on shipping containers was generally valid with respect to interstate commerce, but application of the tax to particular containers that were used in international commerce was disallowed. In applying the critical constitutional distinction between interstate and foreign commerce, *Japan Line* observed that "the Founders intended the scope of the foreign commerce power to be the greater." 441 U.S. at 448.

To allow states to circumvent *Reyno* by entitling foreign plaintiffs to bring actions in the United States to take advantage of favorable American products liability laws would make the incidence of such actions depend upon the vagaries of individual states' attitudes toward federally-established doctrine and would thus prevent the federal government from "speaking with one voice" when regulating foreign commerce.

The very grant of plenary review in *Reyno*, however, suggested the importance of a substantive national policy concerning forum selection for international litigation. If forum non conveniens in international products liability cases were to be governed by state law, it would seem highly unusual for this Court to have granted plenary review in *Reyno* simply to re-evaluate the interpretations of "substantive"[14] state law by the lower federal courts. This Court found it unnecessary explicitly to decide whether under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), state or federal doctrine was controlling and

[14]Under 28 U.S.C. § 2072, lower federal courts sitting in diversity apply federal law on matters of "practice and procedure." *See Hanna v. Plumer*, 380 U.S. 460 (1965).

further noted that Pennsylvania and California forum non conveniens law were virtually identical to federal law. 454 U.S. 248 n.13. However, the Court's reasoning strongly suggests that the law applied was federal; *Reyno* relied upon no Pennsylvania or California cases or statutes, but only previous federal decisions.

The rule that this Court adopted in *Reyno* should be binding in state and federal courts alike. Given the importance of this issue to both the outcome and the substantive law controlling the case, it is respectfully submitted that the result in *Reyno* was not intended as a "procedural" exception to *Erie*, binding only in federal courts. *Cf. Klaxon Co. v. Stentor Electric Manufacturing Co.*, 313 U.S. 487 (1941) (choice of law decisions should not vary between state and federal courts). Instead, *Reyno* should also be binding in state courts because *Erie* does not require deference to state law in questions concerning international affairs. *Accord Banco Nacional de Cuba v. Sabbatino*, 376 U.S. 398, 425 (1964) (act of state doctrine precludes state and federal court scrutiny of foreign government's intraterritorial confiscations).

The *Reyno* opinion demonstrates that this Court was keenly aware that what was at stake was the proper disposition of international, not domestic, cases. Forum changes among the district courts in domestic litigation are controlled by the interdistrict transfer provision of 28 U.S.C. § 1404(a). Yet this Court emphasized that cases construing 28 U.S.C. § 1404(a) do not control forum non conveniens determinations. Specifically, this Court rejected application of *Van Dusen v. Barrack*, 376 U.S. 612 (1964), which holds that interdistrict transfer should not result in a change of applicable substantive law. *Reyno*, 454 U.S. at 253-254.

The application of *Reyno* to all international litigation, regardless of whether an action has been removed to federal court (e.g., *Reyno*) or not (e.g., the present case), best serves the principle underlying *Erie* — that the result of a diversity action should not depend on whether the case has been removed.

In sum, *Reyno* established national forum non conveniens policy applicable to international litigation as follows: The prospective advantage of American substantive law more favorable to recovery does not automatically entitle a foreign plaintiff to maintain litigation in the United States when an American forum is an inconvenient place to conduct the litigation. Accordingly, California's attempt to make American exports carry the burden of its liberal liability law wherever they may be distributed throughout the world defies national supremacy and is an ultra vires and unconstitutional interference with foreign commerce.

C. The Threatened Burden on the Global Competitiveness of American High-Technology Exports Is a Matter of Pressing National Concern.

California's attempt to saddle high-technology exports with the burden of its products liability law comes at a time when exports are assuming enormous importance to the nation while facing substantial competitive challenges in the world market.

The future strength of the United States' economy depends, in significant part, upon the ability of this country to compete in the world market for high-technology products. This fact is forcefully documented in the Report of the President's Commission on Industrial Competitiveness, *Global Competition: The New Reality* (two volumes, 1985). As emphasized therein, the challenge of

American competitiveness in the world market is "*the* economic agenda for the next decade." I *Global Competition* 3 (emphasis in original).[15]

Exports have gained a substantial and increasing importance to the national economy. Currently, nearly one-fifth of our industrial production is exported, amounting to $220 billion in 1984. I *Global Competition* 9; II *Global Competition* 205. The need for increased exports is underscored by the fact that 70 percent of domestically produced goods now compete with merchandise from abroad. I *Global Competition* 9.

High-technology exports have particular present and future significance. The high-technology area has been the fastest growing and most competitive of all U.S. manufacturing sectors, with high-technology exports approaching one-half of all U.S. exports of manufactured goods. U.S. Dept. of Commerce, International Trade Admin., *An Assessment of U.S. Competitiveness in High Technology Industries* 3-4 (1983); II *Global Competition* 306-307. The future importance of this sector is emphasized by the rapidly growing world demand for high-technology products and by the fact that advanced technology is the greatest comparative advantage held by the United States in its effort to compete with the rest of the world. I *Global Competition* 16-17; II *Global Competition* 14, 30, 62, 90, 279, 306-307.

Despite the critical importance of exports to the national economy, the ability of the United States to compete in the world market has suffered a serious decline over the last two decades. I *Global Competition* 9-16; II

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[15] "Our ability to compete in world markets is the very foundation for our rising standard of living" and is "vital in attaining . . . strong national security." I *Global Competition* 6-7.

Global Competition 174-175. Even the U.S. high-technology sector, which far outperforms the U.S. economy as a whole, has declined in international market position. Market share for the high-technology group — and for nearly all individual industries — has fallen, while foreign competition in high technology has increased dramatically. *Assessment of U.S. Competitiveness* 9-10; I *Global Competition* 13, 16; II *Global Competition* 308-309.

Because of its far-reaching practical consequences, as well as its doctrinal importance, this case merits plenary review by this Court.

II

CALIFORNIA'S INTERFERENCE WITH THE CHOSEN SOCIAL POLICIES OF FOREIGN GOVERNMENTS DISREGARDS FEDERALLY-ESTABLISHED PRINCIPLES OF INTERNATIONAL COMITY AND UNCONSTITUTIONALLY ABRIDGES THE EXCLUSIVE GRANT OF FOREIGN RELATIONS POWER TO THE FEDERAL GOVERNMENT.

A. Federally-Established Principles of International Comity Proscribe Overbearing Judicial Interference with the Public Policies of Foreign Governments.

The United States Court of Appeals for the Ninth Circuit observed in *Timberlane* that the extraterritorial application of American laws has been a matter of great concern for other nations and that they "have sometimes resented and protested, as excessive intrusions into their own spheres, broad assertions of authority by American courts." 549 F.2d at 609. The judiciary needs to recognize the foreign implications of its actions and, where appro-

priate, to exercise self-restraint as a matter of international comity and fairness. *Timberlane*, 549 F.2d at 613.

When discussing the act of state doctrine, this Court has described the gravity of comity considerations:

> "The principle that the conduct of one independent government cannot be successfully questioned in the courts of another . . . rests at last upon the highest considerations of international comity and expediency. To permit the validity of the acts of one sovereign State to be reexamined and perhaps condemned by the courts of another would very certainly 'imperil the amicable relations between governments and vex the peace of nations.' "

Sabbatino, 376 U.S. at 417-418 (quoting *Oetjen v. Central Leather Co.*, 246 U.S. 297, 303-304 (1918)).

This Court indicated in *Sabbatino* that the need for judicial self-restraint varies with the extent to which an issue implicates foreign relations. *Sabbatino*, 376 U.S. at 428. The Ninth Circuit adhered to this analysis in establishing the following guideline for limiting the reach of the federal antitrust laws in the international context: Extraterritorial jurisdiction will not be asserted where the interest of the United States in adjudicating a dispute is not sufficiently strong when compared to that of the foreign government. *Timberlane*, 549 F.2d at 613-615.

The *Timberlane* court also cautioned that judicial concern for comity is particularly needed in international litigation between private parties. The judiciary's cognizance "of the possible foreign implications of its action . . . . is especially required in private suits . . . for in these cases there is no opportunity for the executive branch to weigh the foreign relations impact." 549 F.2d at 613. At the point where the interference with the policies of a

foreign government is not outweighed by the interest of the United States in adjudicating a dispute, "the foreign harmony incentive for restraint [is] too strong to justify an extraterritorial assertion of jurisdiction." *Timberlane*, 549 F.2d at 609.

B. Federally-Established Principles of International Comity Are Binding on State Courts.

In *Sabbatino*, this Court left no doubt that comity principles articulated by federal authority are binding on state courts.

> If federal authority, in this instance this Court, orders the field of judicial competence in this area for the federal courts, and the state courts are left free to formulate their own rules, the purposes behind the doctrine could be as effectively undermined as if there had been no federal pronouncement on the subject.

Sabbatino, 376 U.S. at 424.

The need for judicial comity and restraint in international litigation derives from the separation of powers doctrine which entrusts the conduct of foreign relations to the federal political branches in general and the national executive in particular. *See Sabbatino*, 376 U.S. at 423. Since the separation of powers amongst the federal branches limits the competence of the federal courts to adjudicate issues of international import, the separation of powers between the states and the federal government in general limits the authority of state courts to an equal or greater extent. *Cf. Sabbatino*, 376 U.S. at 425 n.23. As emphasized by this Court in *Sabbatino*, "we are constrained to make it clear that an issue concerned with a basic choice regarding the competence and function of the Judiciary and the National Executive in ordering our

relationships with other members of the international community must be treated exclusively as an aspect of federal law." 376 U.S. at 425 (footnote omitted).

In the interstate context, states have a great deal of discretion to decide the deference they accord to each other's jurisdiction and laws.[16] The rationale is that states may reciprocate either for or against each other, creating incentives — but not requirements — for interstate comity and cooperation. *See Nevada v. Hall,* 440 U.S. 410, 425-426 (1979).

In the international context, however, one state's decision not to defer to the jurisdiction and laws of another nation has repercussions and consequences for the other states. When a foreign government reciprocates in light of what one state has done, the response is directed against all of the United States. *Japan Line,* 441 U.S. at 450 & n.16. As previously observed by this Court, with respect to international dealings and foreign relations, state lines disappear; as to such purposes, the states do "not exist." *United States v. Belmont,* 301 U.S. 324, 331 (1937). Thus, while governmental power over internal affairs is distributed between the national government and the several states, "[g]overnmental power over external affairs is not distributed, but is vested exclusively in the national government." *Belmont,* 301 U.S. at 330.

The text of the United States Constitution provides ample support for this demarcation. States are expressly forbidden from entering into treaties, alliances, or com-

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[16] *See Nevada v. Hall,* 440 U.S. 410 (1979) (holding that California was not required to give effect to Nevada's statutes concerning sovereign immunity). There are, however, limits on states' discretion in the interstate context, such as the Full Faith and Credit Clause. U.S. Const. art. IV, § 1; *see also Hall,* 440 U.S. at 425.

pacts with foreign governments, and from issuing letters of marque and reprisal. U.S. Const. art. I, § 10, cls. 1, 3 (p. G-1 *infra*). Also restricted is state taxation of imports and exports. U.S. Const. art. I, § 10, cl. 2 (p. G-1 *infra*). *See also Sabbatino,* 376 U.S. at 427 n.25. In sum, California's disregard for federally-established principles of international comity is repugnant to the Constitution.

C. The Judgment Below Creates an Unwarranted State Judicial Interference with the Public Policy of a Foreign Government.

In *Reyno,* this Court found that Scotland had a very strong interest in that litigation. 454 U.S. at 260. Given the factual similarity between *Reyno* and the present case, that finding directs the conclusion that Australia has the predominant public interest in the present case. Under *Reyno,* therefore, California should defer to Australia for adjudication of this action.

The decision below and *Holmes* amount to a per se rule that trial courts may not even consider such competing interests. Because the comparison of differing choice of law rules is given significance only in terms of their effect on the immediate plaintiffs' chances of recovery, these result-oriented decisions of the California Court of Appeal preclude trial courts from taking into account the broader public interests of foreign governments. Indeed, under the reasoning below, the fact that Australia believes it has an interest — and would therefore apply its own law — is enough reason to prevent Australia from being allowed to adjudicate the action.

The facts of this case bring into focus the underlying public interest in balancing the protection of individuals injured by allegedly defective products with the need to encourage the development and availability of high-tech-

nology medical products such as artificial heart valves. In effect, the tort law of each country represents a political judgment and an expression of its social policy in striking a balance between such competing interests.[17]

The outcome of this litigation most affects the future availability and affordability of innovative medical and

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[17]As Professor Atiyah of the University of Oxford has explained in his treatise *Accidents, Compensation and the Law,* determinations about how to prevent accidents and how to compensate the victims thereof call for and reflect political decisions:

> Society never tries to prevent all accidents, even all accidents which cause personal injury, let alone other misfortunes. As a society we often have choices to make between objectives: shall we permit such and such an activity even though we know it will cause accidents? In making choices of this nature, there is again plenty of room of disagreement on fundamental political grounds.

P.S. Atiyah, *Accidents, Compensation and the Law* 10 (3d ed. 1980). This same perspective was forcefully expressed by the district court in *Harrison,* in the context of the forum non conveniens dismissal of products liability litigation over drugs distributed in Great Britain, as follows:

> Each government must weigh the merits of permitting the drug's use and the necessity of requiring a warning. Each makes its own determination as to the standards of degree of safety and duty of care. This balancing of the overall benefits to be derived from a product's use with the risk of harm associated with that use is peculiarly suited to a forum of the country in which the product is to be used. Each country has its own legitimate concerns and its own unique needs which must be factored into its process of weighing the drug's merits, and which will tip the balance for it one way or the other. The United States should not impose its own view of the safety, warning, and duty of care required of drugs sold in the United States upon a foreign country when those same drugs are sold in that country.

510 F. Supp. at 4.

other high-technology imports for Australia. Australia has the predominant interest in setting acceptable levels of risk associated with imported innovative products such as artificial heart valves.[18] The balance between the competing interests of making the benefits of high-technology medical products available to all Australians and deterring the prospect of product-related injury to Australians is a decision appropriately made by Australia, not California.

California does not have a strong interest in this case. The product in question was never distributed or used in California and no Californians were injured. The risks associated with an innovative export are most likely to result in injury in the importing state, not the exporting state. As with every other 70-degree valve, which was exported only and never sold or distributed in California or elsewhere in the United States, the heart valve at issue in this action never posed any risk of harm in California. Having been exported to Australia, both its benefits and its risks were directed exclusively at Australian patients.

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[18]On remarkably similar facts, the district court in *Fraizer* granted the forum non conveniens dismissal of a products liability action brought by Danish citizens for the malfunction of an artificial heart valve exported by St. Jude Medical, a Minnesota resident manufacturer. The court emphasized Denmark's greater governmental interest in adjudicating litigation arising from the failure of the valve in that country as follows:

> . . . Denmark has a significant interest in setting the standards that a foreign manufacturer must meet to sell products there. Plaintiffs reside in Denmark, the valve was marketed and inserted there, and the injury occurred there. Under these circumstances, it is most appropriate to judge the defendant's conduct by the standards of the community affected by its actions.

609 F. Supp. at 1131-1132.

In contrast to California's law of strict products liability, Australia's adherence to the traditional principles of negligence liability is more conducive to innovation and development of new, albeit perhaps more risky, products. California's strict liability scheme may reduce the susceptibility of California patients to uncertain risks but at the cost of deterring the development of new innovative products.

The public policies of foreign governments which are geared toward more rapid innovation and use with the reciprocal risks and benefits ought not to be displaced by American products liability standards, especially for high-technology medical products for which foreign countries depend in large part upon American manufacturers. In a recent and well-considered decision granting a forum non conveniens motion in the Bhopal litigation, the court declined to pass judgment on whether Indian laws were sufficient to protect Indian citizens from harm. "It would be sadly paternalistic, if not misguided, of this Court to attempt to evaluate the regulations and standards imposed in a foreign country." *Union Carbide Corp. Gas Plant Disaster*, 634 F. Supp. at 864.[19] As the court in *Timberlane* noted, "the legitimacy of each nation's inter-

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[19]In agreement is the district court's perspicacious conclusion in *Harrison* that it would be "an inappropriate usurpation of a foreign court's proper authority to decide a matter of local interst, for a court in this country to set a higher standard of care than is required by the government of the country in which the product is sold and used." 510 F. Supp. at 5.

In stark contrast are the parochial decisions of the California Court of Appeal below and in *Holmes* to sit in judgment over the liability standards for products used around the world. In *Holmes*, the court went so far as to castigate a foreign sovereign (Great Britain) for its choice of products liability policy. 156 Cal. App. 3d at 385-387.

est is assumed. It is merely the relative involvement and concern of each state with the suit at hand that is to be evaluated in determining whether extraterritorial jurisdiction should be exercised by American courts as a matter of comity and fairness." *Timberlane*, 549 F.2d at 615 n.34.

On balance, because Australia has a much stronger interest in the public policy impact of this litigation, federally-established principles of international comity direct that California refrain from proceeding to adjudicate this action.

CONCLUSION

Dismissal of this appeal would invite the states to (1) impose a substantial burden on foreign commerce and (2) impede the public policies of foreign governments which encourage imports from the United States.

Probable jurisdiction should be noted. Indeed, it may be appropriate for this Court to reverse summarily given the clear discrepancy between the decision below and *Reyno*. If, however, the Court determines that it lacks jurisdiction to hear the case on appeal or to reverse summarily, the questions presented are substantial nonetheless and certiorari should be granted under 28 U.S.C. § 2103.

Respectfully submitted,

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November 17, 1986

APPENDIX A

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
SECOND APPELLATE DISTRICT
DIVISION FOUR

Filed June 9, 1986
As modified June 19, 1986

JAMES FOGARTY CORRIGAN, et al.,
Plaintiffs and Appellants,
v.
BJORK SHILEY CORPORATION,
Defendant and Respondent.

APPEAL from a judgment of the Superior Court of Los Angeles County. Robert H. O'Brien, Judge. Reversed.

Magana, Cathcart, McCarthy & Pierry, Brian R. Magana and Deborah Mitzenmacher, for Plaintiffs and Appellants.

Kindel & Anserson [sic], Palmieri, Tyler, Wiener & Wilhelm, Frank C. Rothrock, and Paul R. Johnson, for Defendant and Respondent Shiley, Inc.

Australian James Corrigan and his two sons (appellants) appeal the trial court's order of a stay of their action for wrongful death brought against California-based Bjork-Shiley Corporation (respondent), a manufacturer of a heart valve prosthesis, based upon the doctrine of forum non conveniens. We reverse the stay order.

FACTUAL AND PROCEDURAL BACKGROUND

This is an action for wrongful death arising out of the demise of Elsie Joan Corrigan, age 49, on September 20, 1982. Mrs. Corrigan was a citizen and resident of New South Wales, Australia. On September 8, 1982, she had undergone a mitral (heart) valve replacement with the implantation of a Bjork Shiley disc prosthesis with a 70 degree opening angle. The surgery was performed by Australian doctors in an Australian hospital. This particular heart valve prosthesis was imported from its sole manufacturer, Bjork-Shiley Corp. (a California corporation with its principal place of business in Irvine, California).

On September 20, several of the components of the valve allegedly fragmented and separated from the valve, entering Mrs. Corrigan's circulatory system. A resulting blockage allegedly caused cardiac arrest from which she could not be resuscitated.

Mrs. Corrigan was survived by appellants, who brought an action in Los Angeles County for wrongful death on September 19, 1983. The complaint alleged products liability negligence, strict liability and breach of express and implied warranties. Respondent answered the complaint without alleging third party negligence.

Discovery ensued, and on June 14, 1985, respondent filed a motion to dismiss based on the grounds that Los Angeles County was an inconvenient forum and that Australia was the proper alternative forum. Respondent presented some evidence that the hospital had removed the 70-degree valves from the rigid container designed to protect the valves from damage during shipping, sterilization and other handling. Respondent contended that the hospital apparently then wrapped the 70-degree valves in

paper table napkins and paper bags to sterilize them, contrary to respondent's written instructions regarding recommended sterilization procedures.

Respondent also presented evidence that the 70-degree valve was exported to Australia under federal law and was never sold or distributed in the United States. Respondent stopped the manufacture and sale of the valve in January 1983, pursuant to FDA withdrawal of approval for manufacture.

Respondent also stipulated to submit to Australian jurisdiction and to pay any judgment rendered against it there, to comply with all discovery orders, and to exercise its best efforts and pay the costs of making any 10 of its past or present employees available to testify at trial in Australia.

In its opposition, filed July 2, 1985, appellants presented considerable evidence of valve design failure, including the fact that the U.S. Department of Health and Resources concluded after metallurgical tests that welding problems caused the valve failures, necessitating total redesign. Appellants also contended that the FDA withdrew permission to export the valve because of problems inherent in the valve itself.

Appellants also presented evidence that respondent possesses at least 20 failed valves which had been exported to eight different countries, and that the 70-degree valves were made by retooling 60-degree valves which were sold in the United States. Litigation over alleged failures in the 60-degree valves is apparently pending in this country.

On July 10, 1985, the court denied the motion to dismiss, but stayed the action pursuant to Code of Civil Procedure section 410.30, subdivisioin (a) so that it

might be brought in Australia; finding that the prejudice to respondent was greater if the action remained in California than that to appellants if it were brought in Australia. This appeal followed.

CONTENTION

Appellants contend that the trial court abused its discretion by staying the action based upon the doctrine of forum non conveniens.

DISCUSSION

I. Doctrine of Forum Non Conveniens

The doctrine of inconvenient forum is codified in Code of Civil Procedure section 410.30, subdivision (a) which provides: "When a court upon motion of a party or its own motion finds that in the interest of substantial justice an action should be heard in a forum outside this state, the court shall stay or dismiss the action in whole or in part on any conditions that may be just."

"[T]he doctrine of inconvenient forum is not jurisdictional [citations]" (*Pham* v. *Wagner Litho Machinery Co.* (1985) 172 Cal.App.3d 966, 972), and thus our inquiry presupposes that jurisdiction in either forum is good. [1]

The principle of forum non conveniens is that a court may resist imposition upon its jurisdiction even when jurisdiction is authorized by a venue statute. (*Brown* v. *Clorox Co., supra,* 56 Cal.App.3d 306, 310.) "That doc-

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[1]It is recognized that one of the appropriate forums in which an action against a corporate defendant may be brought is the state of its incorporation or principal place of business. (*Brown* v. *Clorox Co.* (1976) 56 Cal.App.3d 306, 311.)

trine is typically applied to litigation where all of the parties are out-of-state residents and where the cause of action arose outside the forum state. [Citation.]" (*Thomson v. Continental Ins. Co.* (1967) 66 Cal.2d 738, 742.)

The act of staying an action is an act of discretion which "may not be arbitrary; it must be exercised in conformity with the spirit of the law and in a manner to subserve and not impede the ends of substantial justice. [Citation.]" (*Great Northern Ry. Co.* v. *Superior Court* (1970) 12 Cal.App.3d 105, 110.) It is regarded as a " 'drastic remedy to be exercised . . . with caution and restraint.' [Citation.]" (*Hemmelgarn* v. *Boeing Co.* (1980) 106 Cal.App.3d 576, 580.) Where the court has abused its discretion, the stay must be lifted. (*Brown* v. *Clorox Co., supra,* 56 Cal.App.3d 306, 313-314.) However, the discretion of the trial court should be disturbed on appeal only when the order is unsupported by substantial evidence. (*Dendy* v. *MGM Grand Hotels, Inc.* (1982) 137 Cal.App.3d 457, 460.)

In making its determination to stay or dismiss the court may take into account " 'any consideration which legitimately bears upon the relative suitability or convenience of the alternative forums.' [Citation.]" (*Dendy* v. *MGM Grand Hotels, Inc., supra,* 137 Cal.App.3d at 461.)

The Judicial Council comment to Code of Civil Procedure section 410.30 states that two considerations are most important: first, that " 'since it is for the plaintiff to choose the place of suit, his choice of a forum should not be disturbed except for weighty reasons. . . . ' [Citations.] The second is that 'the action will not be dismissed unless a *suitable* alternative forum is available to the plaintiff. . . .' [Citation]" (*Holmes* v. *Syntex Laboratories, Inc.* (1984) 156 Cal.App.3d 372, 379.) "The remaining factors have been characterized as involving either the private

interests of the parties or the public's interest in the litigation. [Citation.]" (*Ibid.*) The factors are numerous.[2] "[B]asically the court looks to the relative convenience and fairness to the parties and witnesses in favoring one forum over another, which forum will best serve the interests of judicial efficiency, which forum is most able to

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[2]"They include the amenability of the parties to personal jurisdiction in this state and in the alternative forum; the relative convenience to the parties and trial witnesses of the competing forums; the differences in the conflict of law rules applicable in the competing forums; the selection of a convenient, reasonable and fair place of trial; defendant's principal place of business; the extent to which the cause of action arose out of events related to this state; the extent to which any party will be substantially disadvantaged by a trial in either forum; the relative enforceability of judgments rendered in this state or the alternative forum; the relative inconvenience to witnesses and relative expense to parties of proceeding in this state or the alternative forum; the significance and necessity of a view by the trier of fact of physical evidence not conveniently movable from the alternative forum; the extent to which prosecution of the action in this state would place a burden upon this state's judicial resources equitably disproportionate to the relationship of the parties or cause of action to this state; the extent to which the relationship of the moving party to this state obligates him to participate in judicial proceedings here; this state's interest in providing a forum for some or all of the parties; this state's public interest in the litigation; the avoidance of multiplicity of actions and inconsistent adjudications; the relative ease of access to sources of proof; the availability of compulsory process for attendance of witnesses; the relative advantages and obstacles to a fair trial; the burden upon jurors, local court and taxpayers of a jurisdiction having a minimal relation to the subject of the litigation; the difficulties and inconveniences to defendant, the court and jurors incident to the presentation of evidence by deposition; and the availability of the suggested forum. [Citation.] [¶] A court may not consider, however, the probability, if such exists, that a California jury may be more generous in its award than the proper forum. [Citation.]" (*Hemmelgarn* v. *Boeing Co., supra,* 106 Cal.App.3d at pp. 584-585.)

obtain jurisdiction over parties and compel witnesses to testify, and the relative interest of each state in adjudicating the issue. [Citations.]" (*Dendy* v. *MGM Grand Hotels, Inc., supra,* 137 Cal.App.3d at pp. 461-462, fn. omitted.)

II. Neutral Factors

In approaching the balancing test required in the instant action, we first dispose of the factors which are basically neutral and do not require extensive discussion before taking up the two considerations deemed important by the Judicial Council and other factors which indicate a preference for a particular forum.

The Australian plaintiffs are willing to come to California in the prosecution of their action and to submit to this state's jurisdiction, whereas respondent has stipulated to submit to jurisdiction and pay any judgment that might be rendered in Australia. Thus, this factor appears neutral in our weighing process.

The present California action was commenced well within our state's statute of limitations; the applicable statute of limitations in Australia is six years (expiring on September 19, 1988) and that alternative forum is available. Another basically neutral factor.

As to the relative convenience to parties and witnesses of trial in Australia, both sides are willing to shoulder the burden of trial in the forum which is less convenient from the perspective of their respective residences, and neither forum is more convenient from the standpoint of all the witnesses; therefore, this factor is essentially neutral. (See *Brown* v. *Clorox Co., supra,* 56 Cal.App.3d 306, 312.) Each party is also willing to assume the expense of trial in the less convenient forum, so this factor is also neutral. Further, their relative ease of access to sources of proof

would be about equally enhanced were trial to commence in their respective preferred forums. Any judgment rendered in either forum will be enforceable. The difficulty to the moving party, court and jurors created by the necessity of employing deposition testimony is not oppressive. Finally, the case does not turn on a view by the trier of fact of physical evidence which cannot be moved from the site of the accident.[3]

We turn then to the factors which require further analysis in reviewing the propriety of the trial court's decision.

We comment at the outset upon a recent decision of the Court of Appeal, First Appellate District, *Holmes v. Syntex Laboratories, Inc., supra,* 156 Cal.App.3d 372. In *Holmes,* British citizens filed a class action against Syntex, a Delaware corporation with its principal place of business in California, and its British affiliate, based upon Syntex's alleged "failure to warn" of known dangerous side effects in its oral contraceptives ingested by plaintiffs.

In *Holmes*, the court found that Britain was not a suitable alternative forum and that trial should be held in California, citing, among other reasons, the great weight given plaintiff's choice of forum regardless of the fact they were foreign residents, the inadequacies of British law evidenced in its lack of strict products liability law,

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[3]This case principally involves a small medical device and related surgical procedures, and is thus factually comparable to products cases such as *Holmes v. Syntex Laboratories, Inc., supra,* 156 Cal.App.3d 372, 379 (oral contraceptives) and *Brown v. Clorox Co., supra,* 56 Cal.App.3d (drain cleaner); rather than to cases such as *Hemmelgarn v. Boeing Co., supra,* 106 Cal.App.3d 576 (plane crash), or *Dendy v. MGM Grand Hotels, Inc., supra,* 137 Cal.App.3d 457 (hotel fire), where a view of the accident site might be significant.

the defendant's presence in and relationship to California, and California's interest in regulating the foreign marketing of defective products.

In our own case, with its important products liability basis, appellants strenuously urge that *Holmes* virtually dictates a reversal of the stay, while respondents urge that *Holmes* is anomalous and other decisions, including those handed down in federal court, mandate that the stay imposed by the trial court be upheld.

Concerning the first of the two factors deemed most important by the Judicial Council, the rule of "substantial deference" given to plaintiff's choice of forum, it has been said that plaintiff's choice "should be respected unless equity weighs strongly in favor of the defendant. [Citations.]" (*Dendy v. MGM Grand Hotels, Inc., supra,* 137 Cal.App.3d 457, 460; accord *Great Northern Ry. Co. v. Superior Court, supra,* 12 Cal.App.3d 105, 110; *Appalachian Ins. Co. v. Superior Court* (1984) 162 Cal.App.3d 427, 435.)

Although the rule of substantial deference is not eliminated when plaintiff is foreign (either noncitizen or nonresident), the deference accorded his choice is less than that accorded the choice of a California resident. This conclusion is obvious in the fact that "except in extraordinary cases a trial court has no discretion to dismiss an action brought by a California resident on grounds of forum non conveniens." (*Archibald v. Cinerama Hotels* (1976) 15 Cal.3d 853, 858.) This limitation of the doctrine "does not rest on any conclusion derived from a balancing of conveniences; it reflects an overriding state policy of assuring California residents an adequate forum for the redress of grievances." (*Id.* at p. 859.) Further, in *Bechtel Corp. v. Industrial Indem. Co.* (1978) 86 Cal.App.3d 45, 52-53, it was said that the trial court has no discretion to

stay *or* to dismiss where both plaintiff and defendant are California residents. This rule was not applied in multiparty litigation where some parties were not California residents. (See *Dendy v. MGM Grand Hotels, Inc., supra,* 137 Cal.App.3d 457, 461.)

Therefore, in the case at bench, although the Australian plaintiffs' choice of a California forum is entitled to some deference, this consideration cannot dominate our decision.

III. The Suitability of the Alternative Forum

We next concern ourselves with the second consideration found important in the Judicial Council comment and in *Holmes v. Syntex Laboratories, Inc., supra,* 156 Cal.App.3d 372, 381, the suitability of the alternative forum.

"The effect of different conflict of law rules or some other 'substantial disadvantage' from a change in forum may be of such a character as to deprive the plaintiff of a 'suitable' alternative forum. [Citation.]" (*Holmes v. Syntex Laboratories, Inc., supra,* 156 Cal.App.3d 372, 381.)

In its analysis of the difference between state and federal law after the United States Supreme Court decided *Piper Aircraft Co. v. Reyno* (1981) 454 U.S. 235, 250-251, the *Holmes* court stated that California attaches far greater significance to the possibility of an unfavorable change in applicable law resulting from a forum non conveniens dismissal (*Holmes v. Syntex Laboratories, Inc., supra,* 156 Cal.App.3d at p.381) than the federal rule announced in *Piper.* In *Piper* the United States Supreme Court said that the possibility of an unfavorable change in law is not relevant unless "the remedy provided by the alternative forum is so clearly inadequate or unsatisfac-

tory that it is no remedy at all." (*Piper Aircraft Co. v. Reyno, supra,* 454 U.S. at p. 254.) The rationale stated for this finding was that since ordinarily "plaintiffs will select that forum whose choice-of-law rules are most advantageous[,] . . . if the possibility of an unfavorable change in substantive law is given substantial weight . . ., dismissal would rarely be proper." (*Id.* at p. 250.)

The *Piper* court observed that choice of law analysis would become extremely important and courts would frequently be required to interpret law of a foreign jurisdiction and would have to compare rights, remedies and procedures available in each forum, which forum non conveniens was designed to avoid. (*Id.* at p. 251.)

It is clear, however, that California courts have demonstrated a willingness to assume the burden of resolving conflict of laws problems and will not invoke forum non conveniens doctrine simply to avoid a choice of law analysis. (See *Brown v. Clorox Co., supra,* 56 Cal.App.3d 306, 313.)

In *International Harvester Co. v. Superior Court* (1979) 95 Cal.App.3d 652, 659-662, the subject party of a cross-action for indemnity in a personal injury case filed in California moved for dismissal in favor of a Kansas forum where the accident occurred. The appellate court observed that under Kansas conflict of law rules a Kansas court would apply its own law of indemnity. Since it was at least an open question whether the cross-complainants would have *any* right of indemnity in Kansas, the court opined: "If they do not, the difference in applicable substantive law virtually dictates trial in California." (*Id.* at p. 660.)

In *Chavarria v. Superior Court* (1974) 40 Cal.App.3d 1073, 1076, the court engaged in a choice of law analysis

to demonstrate that removal to Texas was proper. The *Chavarria* court found that in Texas choice of law was determined by the law of the place of injury, in this case California. Since damages were considered a substantive matter, plaintiffs would not lose the double damage remedy provided under California law by transfer of the case to Texas. (*Ibid.*)

Thus, choice of law analysis is used in California forum non conveniens inquiries to determine whether the plaintiff or cross-complainant would effectively be denied a remedy, which would dictate trial here, as in *International Harvester*, or whether the remedy would be seriously affected, as in *Chavarria*, the absence of such an impact being an important factor in allowing a dismissal or stay of California trial.

Under California law, the purpose of comparing the differences in conflict of law rules and the differences in substantive law which will be applied, once the choice of law has been made in each alternative forum is not simply to decide which forum would provide the most advantageous law from the viewpoint of the plaintiff. To the extent *Holmes* explicitly or implicitly directs otherwise, we decline to follow it.

Several considerations support this conclusion.

First, the existence of unsettled procedural questions in the alternative forum does not make it unsuitable. In *Archibald v. Cinerama Hotels, supra*, 15 Cal.3d 853, 862, where Hawaii was the proposed alternative forum the court said: "[T]he existence of unsettled questions of Hawaiian procedure does not compel the trial court to conclude as a matter of law that Hawaii is not a suitable alternative forum. Uncertainties such as this concerning the suitability of the foreign forum have prompted our

holding that a court cannot dismiss a suit by a true California plaintiff, but can stay that suit: the staying court can resume proceedings if the foreign forum proves unsuitable. [Citation.] California's appetite for litigation must not be so gluttonous as to compel it to engage in the trial of causes that are found by the court of first resort to be more conveniently resolved elsewhere, since if redress in the foreign jurisdiction proves abortive, California courts retain the option to resume proceedings." (Fn. omitted.)

Secondly, we bear in mind the often-cited proposition that the "probability that one forum may be more generous than the other may not be considered [citation], . . ." (*Hemmelgarn v. Boeing Co. supra*, 106 Cal.App.3d 576, 588; accord *Great Northern Ry. Co. v. Superior Court, supra*, 12 Cal.App.3d 105, 112; *Jagger v. Superior Court* (1979) 96 Cal.App.3d 579, 589.) In *Hemmelgarn v. Boeing Co. supra*, 106 Cal.App.3d at page 588, this proposition was invoked to demonstrate that where competing policy interests pointed to the alternative forum as more appropriate, the fact that less damages would be available therein was not controlling.

Finally, our own choice of law doctrine reveals a respect for the law of foreign jurisdictions which does not seek to weigh the worth of the social policy reflected in the laws of the respective forums, but instead focuses on which forum's governmental interest will be the more impaired if its law is not applied.

IV. The Differences in Conflict of Law Rules in Each Forum

A. Australian Law Would Be Applied in Australia.

Australia follows the "lex fori" rule of choice of law: the law of the forum applies to all tort actions brought in

Australia, with exceptions not important here. (See *Walker v. W. A. Pickles Pty. Ltd.* (1980) 2 N.S.W.L.R. 281, 288-289; *Anderson v. Eric Anderson Radio and T.V. Pty. Ltd.* (1965) 164 C.L.R. 20, 40-42.)

Thus Australia will employ its own law. Were the case to be tried in Australia, discovery is not as liberal as are the same procedures in California; although trial in California would also be affected by Australian rules governing a foreign court's right to discover certain matters existent in Australia. (See *Application of Forsyth* (1984) 2 N.S.W.L.R. 327; *National Employers' Mutual General Association Ltd. v. Waind & Hill* (1978) 1 N.S.W.L.R. 372.) Substantively, appellants' causes of action based on strict liability and breach of warranty would be circumscribed, as would certain elements of damage. (See *Fletcher v. Topper's Drinks Pty. Ltd.* (1981) 2 N.S.W.L.R. 916; *Rowe v. Scanlan* (1969) 1 N.S.W.R. 43; *Naum v. Nominal Defendant* (1974) 2 N.S.W.L.R. 14.)

B. California Choice of Law Principles Indicate that California Law Would Be Applied if the Trial is Held in California.

California choice of law principles indicate that California law would govern this action were it to be tried in this state. California choice of law rules rest on an analysis of the respective interests of the states or countries involved; the so-called "governmental interest" approach, the objective of which is " 'to determine the law that most appropriately applies to the issue involved.' [Citation.]" (*Hurtado v. Superior Court* (1974) 11 Cal.3d 574, 579-580, fn. omitted.) If both California and the foreign forum[4] have a strong interest in applying their own law,

[4] " 'The governmental interests approach is applicable not only to situations involving multistate contacts but also to those involving a

the court engages in a "comparative impairment" analysis, applying the law of the state whose interest would be more impaired "if its policy were subordinated to the policy of the other state." (*Bernhard v. Harrah's Club* (1976) 16 Cal.3d 313, 320; see discussion in *American Bank of Commerce v. Corondoni* (1985) 169 Cal.App.3d 368.)

"The Court *does not* 'weigh' the conflicting governmental interests in the sense of determining which conflicting law manifested the 'better' or 'worthier' social policy of the specific issue." (*Camp v. Forwarders Transport, Inc.* (C.D.Cal. 1982) 537 F.Supp. 636, 638; accord *Bernhard v. Harrah's Club, supra,* 16 Cal.3d 313, 320.)

Although California has a general preference for its own law (*American Bank of Commerce v. Corondoni, supra,* 169 Cal.App.3d 368, 372) in *Camp v. Forwarders Transport, Inc., supra,* 537 F.Supp. at pages 638-639, the court concluded that once a conflict is found, California applies the "comparative impairment test, without any bias, preference or presumption against the law of the foreign state," based upon *Cable v. Sahara Tahoe Corp.* (1979) 93 Cal.App.3d 384, and *Bernhard v. Harrah's Club, supra,* 16 Cal.3d 313.

Thus, it is clear that our own conflict of law rules require that we concentrate more on the comparative impairment of respective state interests than on the purported inadequacies of Australian tort law.

It has been repeatedly asserted that California has an important interest in regulating products manufactured in California. (See *Hemmelgarn v. Boeing Co., supra,* 106

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state of the United States vis-a-vis a political entity of a foreign country.' [Citations.]" (*Hernandez v. Burger* (1980) 102 Cal.App.3d 795, 798, fn. 1.)

Cal.App.3d 576, 588; *Holmes v. Syntex Laboratories, Inc., supra*, 156 Cal.App.3d 372, 389; *Brown v. Clorox Co., supra*, 56 Cal.App.3d 306, 313.) While Australia has an interest in applying its law to injuries from products occurring within its borders, that interest would not be impaired by application of California law. Australia would have little interest in prohibiting a complete remedy for injury to its own citizens, whereas "when the defendant is a resident of California and the tortious conduct giving rise to the wrongful death action occurs *here*, California's deterrent policy of full compensation is clearly advanced by application of its own law." (*Hurtado v. Superior Court* (1974) 11 Cal.3d 574, 584, italics added.) Under these circumstances, California law would be applicable if trial were held here, and the analysis of our "governmental interest" in the case argues in favor of a California forum.

V. Respondent's Relationship to California

Several related factors also favor trial in California. In the case of a corporate defendant, if either the corporation's place of incorporation or principal place of business is in California, this fact weighs against a forum non conveniens dismissal. (*Holmes v. Syntex Laboratories, Inc., supra*, 156 Cal.App.3d 372, 387; *Hemmelgarn v. Boeing Co., supra*, 106 Cal.App.3d 576, 580; *Brown v. Clorox Co., supra*, 56 Cal.App.3d 306, 311.) Here, the sole named defendant is a California corporation with its principal place of business in California.

Further, respondent has a relationship to this state which imposes upon it "an obligation to participate in judicial proceedings in the courts of this state." (*Great Northern Ry. Co. v. Superior Court, supra*, 12 Cal.App.3d at p. 114.) "[I]t has been held that the mere fact of a defendant's incorporation in the forum state, in itself,

does not give that state any real connection with the controversy so as to require that court to retain jurisdiction." (*Brown v. Clorox Co., supra*, 56 Cal.App.3d 306, 311.) However, where a corporation is actually carrying on business in the state and plaintiffs make an offer of proof concerning defendant's in-state activities which supports the allegation that the tortious conduct occurred in California, the corporate connection with the state is more than tenuous and weighs against dismissal. (See *Holmes v. Syntex Laboratories, Inc., supra*, 156 Cal.App.3d 372, 388.

In *Holmes*, plaintiffs offered factual support that the tortious acts were committed not by the foreign affiliate-intermediary, but by the resident defendant. In our own case, appellants presented the trial court with ample facts as to respondent's manufacture, sale and distribution of its product weighing even more strongly in favor of the requisite connection with California and against dismissal or stay. (See *Holmes v. Syntex Laboratories, Inc., supra*, 156 Cal.App.3d at p. 388.)

Yet another related factor is whether an action brought in this state would impose a burden "which is unfair, inequitable or disproportionate in view of the relationship of the parties or of the cause of action to this state." (*Great Northern Ry. Co. v. Superior Court, supra*, 12 Cal.App.3d at pp. 113-114.) "Every lawsuit tried places a burden upon the courts, but at least one of the functions of courts is to try lawsuits." (*Brown v. Clorox Co., supra*, 56 Cal.App.3d at p. 313.)

In *Hemmelgarn v. Boeing Co., supra*, 106 Cal.App.3d 576, 586-587, the court analyzed the competing governmental interests in holding trial in the alternative forums, and the propriety of burdening the courts in either forum; stating that the "factual underpinning" of the case should

be examined. Although the trial court "does not make a factual finding which is determinative on any issue at trial, it must evaluate the respective involvement of the various defendants in order to weigh the various factors necessary for the exercise of its discretion." In that case, only a nominal connection between the one in-state defendant and the accident was found. (*Id.* at p. 587.)

Here, respondent is not one of numerous named defendants located in this state and abroad, but is the sole named focus of the complaint. The declarations, correspondence and other evidence clearly connect respondent's in-state activities with the subject of the action. In *Brown v. Clorox Co., supra*, 56 Cal.App.3d at page 313, the court found that the relationship of the corporation to California, and its activities in manufacturing, processing, packaging, labeling, distributing and selling products in California and sending products from this state to other states "does not lead to a conclusion that prosecution of this action in this state would 'place a burden on the courts of this state which is unfair, inequitable or disproportionate,' " and the same is true in instant case.

VI. Substantial Disadvantage to Any Party and Avoidance of Multiple Actions

The additional factors remain to be considered. The first is "[t]he extent to which any party will be substantially disadvantaged by a trial in California as contrasted with trial in the forum suggested by the moving party," and the second is "[t]he avoidance of multiplicity of actions and inconsistent adjudication." (*Jagger v. Superior Court, supra,* 96 Cal.App.3d 579, 585-586; accord *Great Northern Ry. Co. v. Superior Court, supra,* 12 Cal.App.3d 105, 113-114.)

In *Holmes v. Syntex Laboratories, Inc., supra,* 136 Cal.App.3d 372, 386-387, the court discussed the substantial disadvantage to plaintiffs if they were required to proceed under British law, which does not recognize strict liability. The court concluded that Britain was not a "suitable" alternative forum.

Since the case at bench is also a products liability action, disadvantage to appellants' theory of the action is manifest in removal to a forum which does not entertain similar substantive products law. Although the case cannot turn on this disadvantage in different substantive law, we may permissibly consider it. However, unlike *Holmes*, this is not a case in which the manufacturer had complete control over a product reaching the ultimate consumer unchanged. In our case the device was subjected to certain sterilization procedures and then implanted by means of a sophisticated surgical procedure, all performed in the alternative forum. The presence and possible contribution of these intermediaries to the eventual failure of the prosthesis cannot be ignored.

Thus, while there is under the *Holmes* substantive law analysis approach, a substantial disadvantage to plaintiff if the trial is convened in the alternative forum, there is also a substantial disadvantage to defendant in the fact that other potential tortfeasors and witnesses are located in the alternative forum and may not be amenable to jurisdiction here.

Although we note this disadvantage to respondent, we do not find that it weighs so heavily in favor of respondent as to counterbalance the factors in favor of trial in this state. The doctors, hospital, and hospital personnel were not named in the action brought by appellants. Respondents thus have no outstanding cross-complaint, and have not taken steps to join any of these parties

either here or in Australia. Further, in answering the complaint, respondent did not make any allegations suggestive of third party negligence or liability.

More importantly, a review of the facts presented thus far does not point to exclusive or even substantial third party liability. In *Hemmelgarn v. Boeing Co., supra*, 106 Cal.App.3d 576, 587-588, the trial court upon review of the facts found only a nominal connection between the in-state defendants and the out-of-state accident and thus the principle of equitable apportionment of liability favored trial elsewhere. There, the predominant liability for the accident appeared to be with several other defendants. In the case at bench, the evidence thus far offered simply does not support a conclusion that third party negligence is a predominant or substantial issue.

Finally, it is inappropriate to shift the forum based upon the fact that respondent *may* join others when it has not taken any steps to do so. The interest and asserted rights implicit in an actual cause of action should not be made subservient to a *potential* cause or causes of action, when the factual basis for such a potential claim is less than obvious. The avoidance of multiple actions is not a dominant consideration here.

When we compare the many factors weighing in favor of trial in this state against those in favor of the Australian forum, we find that the scale is tipped heavily in favor of California and that substantial evidence does not support the trial court's order. The fact that the action was stayed and not dismissed neither changes the balance in favor of this forum nor enhances the appropriateness of the alternative forum. Under these circumstances, we find the trial court abused its discretion in staying the action and reverse the stay order.

DISPOSITION

The trial court's order staying proceedings is reversed.

CERTIFIED FOR PUBLICATION

ARGUELLES, J.

We concur:

McCLOSKY, Acting P.J.

RECANA, J. *

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* Assigned by the Chairperson of the Judicial Council.

APPENDIX B

ORDER DENYING REVIEW

AFTER JUDGMENT BY THE COURT OF APPEAL

2nd District, Division 4, No. B015387

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

IN BANK

CORRIGAN et al.

v.

BJORK SHILEY CORPORATION

Respondent's petition for review DENIED.

Filed: Aug. 20, 1986 Laurence P. Gill, Clerk

BIRD

CHIEF JUSTICE

APPENDIX C

COURT OF APPEAL OF THE STATE OF CALIFORNIA

FOR THE SECOND APPELLATE DISTRICT

DIVISION: 4

Tyler, Wiener & Wilhelm Palmieri [sic]
4000 MacArthur Blvd.
Suite 1000
Newport Beach, CA 92660

RE: Corrigan, James Fogarty (Et Al)
vs.
Bjork Shiley Corporation (Etc) (Et Al)
2 Civil B015387
Los Angeles NO. C468507

* * REMITTITUR NOTICE * *

Notice is hereby given that the Remittitur has been issued this date and that the opinion, decision or order entered in the above entitled cause on 06/09/86 is now final.

* * Reversed In Full. * *

Appellant to recover costs.

CLAY ROBBINS, JR., Clerk
September 22, 1986

APPENDIX D

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

DEPT. 81

Date: July 8, 1985; Honorable Robert H. O'Brien, Judge; I. Brown, Deputy Clerk; Reporter, None.

C 468 507; James Fogarty Corrigan, et al., vs Bjork Shiley Corporation etc., et al.; Counsel for Plaintiff: M. Magana, Brian Magana; Counsel for Defendant: Kindel & Anderson by Frank Rothrock, Paul Johnson.

NATURE OF PROCEEDINGS.

Motion of defendant, Shiley Incorporated to dismiss and for order that interrogatories and answers thereto be filed with the Court; Matter is argued and taken under submission. LATER: Given defendant's offer to transport and produce 10 past or present employees in Australia for trial, it is clear that the prejudice to defendant is greater if the case remains in California for trial than the prejudice to plaintiffs if the case were taken there. Motion to dismiss is denied; however, action is stayed pursuant to CCP 410.30(a) upon condition that action may still be brough [sic] in Australia. Counsel for plaintiff to give notice. Counsel notified by U. S. mail.

Dept. 81 Minutes Entered July 8, 1985 County Clerk; As Amended By Nunc Pro Tunc Order Entered July 22, 1985.

APPENDIX E

OFFICE OF THE CLERK
COURT OF APPEAL
STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT
CLAY ROBBINS, JR., CLERK

DIVISION: 4 DATE: 06/26/86

B015387

Kindel & Anderson
Frank C. Rothrock
4000 MacArthur Boulevard
10th Floor
Newport Beach, CA 92660

RE: Corrigan, James Fogarty (Et Al)
vs.
Bjork Shiley Corporation (Etc.) (Et Al)
2 Civil B015387
Los Angeles No. C468507

PETITION FOR REHEARING DENIED

JUN 26 1986

APPENDIX F

2 CIV B015387

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
SECOND APPELLATE DISTRICT
DIVISION FOUR

JAMES FOGARTY CORRIGAN, BRETT JAMES CORRIGAN and SCOTT JAMES CORRIGAN,
Plaintiffs and Appellants,

vs.

BJORK SHILEY CORPORATION, SHILEY CORPORATION, DOES 1 through 40, inclusive,
Defendants and Respondents.

On Appeal From the Superior Court of California
For the County of Los Angeles
The Honorable Robert H. O'Brien, Judge

(Superior Court Case No. C468507)

NOTICE OF APPEAL TO THE SUPREME COURT OF THE UNITED STATES

PALMIERI, TYLER, WIENER & WILHELM
Frank C. Rothrock
Paul R. Johnson
4000 MacArthur Boulevard
East Tower — Suite 1000
Newport Beach, CA 92660
(714) 851-9400
Attorneys for Defendant
and Respondent
Shiley Incorporated

Filed: Nov. 12, 1986
Clay Robbins, Jr., Clerk

Copy filed with Calif. Superior Court on Nov. 12, 1986

To This Honorable Court and to Plaintiffs and Appellants and Their Attorneys of Record Herein:

NOTICE IS HEREBY GIVEN that Shiley Incorporated, respondent herein, hereby appeals to the Supreme Court of the United States from the judgment of the California Court of Appeal entered on June 9, 1986, and modified on June 19, 1986, which reversed the stay order of the trial court.

This appeal is taken pursuant to 28 U.S.C. § 1257(2).

DATED: November 10, 1986

PALMIERI, TYLER, WIENER
& WILHELM

By /s/ Frank C. Rothrock
Frank C. Rothrock
Attorneys for Defendant and
Respondent
Shiley Incorporated

PROOF OF SERVICE

I, Frank C. Rothrock, a member of the Bar of the Supreme Court of the United States, hereby certifies that on the 10th day of November, 1986, I served a copy of the foregoing NOTICE OF APPEAL TO THE SUPREME COURT OF THE UNITED STATES on plaintiffs, appellants in the California Court of Appeal and appellees in the Supreme Court of the United States, through their counsel of record, by placing a true and correct copy thereof enclosed in a sealed envelope with first-class postage prepaid, in the United States mailbox at 4000 MacArthur Boulevard, Newport Beach, California, addressed as follows:

Brian R. Magana, Esq.
Deborah Mitzenmacher, Esq.
Magana, Cathcart, McCarthy & Pierry
1801 Avenue of the Stars
Suite 810
Los Angeles, CA 90067

I further certify that all parties required to be served have been served.

/s/ Frank C. Rothrock
Frank C. Rothrock
Counsel for
Shiley Incorporated,
Appellant in the
Supreme Court
of the United States

APPENDIX G

UNITED STATES CONSTITUTION, ARTICLE I, SECTION 10.

No State shall enter into any Treaty, Alliance, or Confederation; grant Letters of Marque and Reprisal; coin Money; emit Bills of Credit; make any Thing but gold and silver Coin a Tender in Payment of Debts; pass any Bill of Attainder, ex post facto Law, or Law impairing the Obligation of Contracts, or grant any Title of Nobility.

No State shall, without the Consent of the Congress, lay any Imposts or Duties on Imports or Exports, except what may be absolutely necessary for executing its inspection Laws: and the net Produce of all Duties and Imposts, laid by any State on Imports or Exports, shall be for the Use of the Treasury of the United States; and all such Laws shall be subject to the Revision and Controul of the Congress.

No State shall, without the Consent of Congress, lay any Duty of Tonnage, keep Troops, or Ships of War in time of Peace, enter into any Agreement of Compact with another State, or with a foreign Power, or engage in War, unless actually invaded, or in such imminent Danger as will not admit of delay.

APPENDIX H

21 U.S.C. § 360e. *Premarket approval*

(a) General requirement

A class III device —

(1) Which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(b) Regulation to require premarket approval

(1) In the case of a class III device which —

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain —

(i) the proposed regulation;

(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classificaton of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.

(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this

title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain —

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such

performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary shall refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

(d) Action on application for premarket approval

(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) of this section (except as provided in section 360j(*l*)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report

and recommendation submitted under paragraph (2) of such subsection, shall —

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) (i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an applicaton submitted for a device subject to a regulation promulgated under subsection (b) of this section unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that —

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 360d of this title compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secetary).

(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section, and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g) of this section, of an order of the Secretary approving an application.

(e) Withdrawal of approval of application for premarket approval

(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 360c of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds —

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recomm nded, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 360i(a) of this title, (ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title, or (iii) has not complied with the requirements of section 360 of this title;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was

approved that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 360j(f) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 360d of this title compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(f) Product development protocol

(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c) of this section, such device shall be considered as having an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, he shall refer the proposed protocol to the appropriate panel under section 360c of this title for its recommendation respecting approval of the protocol.

(3) A proposed product development protocol for a device may be approved only if —

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c) of this section; and

(B) the Secretary determines that the proposed protocol provides —

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the

commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 360d of this title to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 360c of this title, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol

is final agency action subject to judicial review under chapter 7 of Title 5.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion —

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1) of this section.

(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that —

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds —

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of

completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(g) Review

(1) Upon petition for review of —

(A) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) of this section revoking an approved protocol, under subsection (f)(6)(B) of this section declaring that an approved protocol has not been completed, or under subsection (f)(7) of this section revoking the approval of a device.

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of Title 5, on the order. The panel or panels which considered the applica-

tion, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of —

(i) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) of this section revoking an approved protocol, under subsection (f)(6)(B) of this section declaring that an approved protocol has not been completed, or under subsection (f)(7) of this section revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a

statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS-18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of Title 5 for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

(h) Service of orders

Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

21 U.S.C. § 360k. *State and local requirements respecting devices*

(a) General rule

Except as provided in subsection (b) of this section, no State or politicial subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if —

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement —

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 381(d)

(d) Exports

(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.

(2) Paragraph (1) does not apply to any device —

(A) which does not comply with an applicable requirement of section 360d or 360e of this title,

(B) which under section 360j(g) of this title is exempt from either such section, or

(C) which is a banned device under section 360f of this title,

unless, in addition to the requirements of paragraph (1), the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.